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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,722	12/10/2004	Peter Neu	00143-00244-US	6059
23416 7590 10/24/2008 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899				
EXAMINER				
ARNOLD, ERNST V				
ART UNIT		PAPER NUMBER		
1616				
MAIL DATE		DELIVERY MODE		
10/24/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/517,722

**Applicant(s)**

NEU ET AL.

**Examiner**

ERNST V. ARNOLD

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 July 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3, 4, 7, 8 and 18 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 3, 4, 7, 8 and 18 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

#### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/29/08 has been entered.

Claims 1, 2, 5, 6 and 9-17 have been cancelled. Claims 3, 4, 7, 8 and 18 are under examination.

#### **Withdrawn rejections:**

Applicant's amendments and arguments filed 7/29/08 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 4, 7, 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Petzelt et al. (WO 00/53192) in view of Thomas (US 6,358,536) and Zapol et al. (US 6,656,452) as evidenced by Adams et al. (Neurology 1987, 37, 1586-1591) and Giller et al. (Abstract: Am J Neuroradiol 1990, 11(1), 177-82).

Applicant claims a method of treating a patient characterized in that a xenon spasmodic is provide in a form of a combination medicament.

#### **Determination of the scope and content of the prior art**

##### **(MPEP 2141.01)**

Petzelt et al. disclose preparations and methods of use of xenon or xenon gas mixtures for treating neurointoxications (a chronic cerebral disorder such as Parkinson's disease; thus an impairment of cognitive performance) in a therapeutically useful concentration (Page 5, paragraph 1; page 11, paragraph 4 and claims 1, 7 and 16, for example). Petzelt et al. teach the use of the gas or gas mixtures where the neurointoxication is craniocerebral trauma (claims 1-3 and 8). Petzelt et al. clearly point towards a method of treating apoplexy and reducing the damage occurring from apoplexy thus encompassing stroke (Claim 4 and page 7, first paragraph). Petzelt et al. clearly direct one to treat ischemia or craniocerebral trauma with the gas mixture over several hours to one day (page 8, second paragraph). The preparation can have a ratio of xenon to oxygen of 80 to 20 percent by volume (Page 8, second paragraph and claims 15 and 17). Administration is by simple inhalation (Page 12, line 1). Methods of mixing the gases are provided (Page 8, paragraphs 3 and 4). Methods of administration are also provided (Page 9,

paragraphs 1 and 2). Petzelt et al. teach a method of producing an inhalable preparation by mixing xenon with another gas harmless for humans (Claim 18).

Thomas teaches methods of alleviating or preventing vasoconstriction or vasospasm in a mammal via administration of a NO source (Abstract). The NO source can be nitroglycerine, arginine and a nitroprusside salt (claims 1, 9 and 10).

Zapol et al. teach use of a therapeutically effective amount of inhaled NO gas for treating ischemia reperfusion, stroke and trauma; for example (Abstract, column 2, lines 50-55 and claim 1). Zapol et al. teach administering a therapeutically effective amount of a second compound that potentiates the therapeutic effect of gaseous nitric oxide (Claim 1). Nitric oxide is a known vasodilator (column 1, lines 22-40).

Adams et al. provide the nexus teaching that ties vasospasm to stroke (aneurysmal subarachnoid hemorrhage) (Abstract).

Giller et al. teach xenon as a cerebral vasodilator (abstract).

#### **Ascertainment of the difference between the prior art and the claims**

#### **(MPEP 2141.02)**

Petzelt et al. do not expressly teach a method of treating spasms such as cerebral vasospasm in a patient with xenon and a spasmolytic wherein xenon is used with the intended purpose of acting as an effective spasmolytic. This deficiency in Petzelt et al. is cured by the teachings of Zapol et al., Thomas as evidenced by Adams et al. and Giller et al.

**Finding of prima facie obviousness**

**Rational and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use an NO source as defined by Zapol et al. or Thomas, in the method of Petzelt et al., for the treatment of spasms such as cerebral vasospasm wherein xenon is used with the intended purpose of acting as an effective spasmolytic and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Petzelt et al. suggests adding another harmless gas, and a therapeutic amount of NO from an NO source would be beneficial to the patient as taught by Zapol et al. and Thomas. As evidenced by Adams et al., it was known at the time of the instant invention that stroke and ischemia and vasospasm were linked. With regard to the new limitation of “wherein xenon is used with the intended purpose of acting as an effective spasmolytic”, it is the Examiner’s position that Petzelt et al. would have known that xenon was a vasodilator and hence “spasmolytic” because of the teachings of Giller et al. Since the methods of Petzelt et al. and Thomas and Zapol et al. are directed to the same purpose it would be obvious to combine xenon and NO especially in view of the fact that Petzelt et al. suggests other gases and Thomas and Zapol et al. teach using NO sources for treating the same conditions. One of ordinary skill in the art would have combined the two compositions, xenon and NO source, in the method of Petzelt et al. It is the Examiner’s position that mixing of xenon and NO gases would read on simultaneous administration and that it is within the purview of one of ordinary skill in the art to determine the best mode of administration on a patient by patient and condition dependent manner where separate or sequential administration might be most favorable for that case.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

One of ordinary skill in the art would have recognized the obvious variation of the instant claims in the copending application because of the overlap in claimed subject matter as stated above.

**Response to arguments:**

Applicant asserts that while Petzelt et al teach using xenon for the treatment of strokes it does not mean that it also intrinsically teach to use xenon for the treatment of spasms and that a patient can suffer a stroke without developing cerebral vasospasms. Respectfully, the Examiner cannot agree. As evidenced by Adams et al. above, there is a patient population that suffers from cerebral vasospasms following a stroke and that patient population would be embraced by the teachings of Petzelt et al.

Applicant asserts that Petzelt et al. only teach xenon for the treatment of neurointoxications which can be caused by stroke and that the person skilled in the art would not

consider xenon for the intended purpose of treating vasospasms (i.e., as a medicament that inhibits the vasoconstriction of blood vessels as a consequence of a blood vessel spasm). The Examiner respectfully cannot agree with that assertion. The art teaches that xenon is a vasodilator. Therefore, the concept of administration of xenon to treat the stroke and the sequelae of stroke, which includes vasospasm, wherein xenon is a spasmolytic is taught in the art .

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).